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10/591,369	08/15/2007	Gerald Adams	1662-3 PCT/US	8067
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HOFFMANN & BARON, LLP 6900 JERICHO TURNPIKE SYOSSET, NY 11791				CRAIGO, WILLIAM A
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/591,369	ADAMS ET AL.	
	Examiner	Art Unit	
	WILLIAM CRAIGO	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 14 August 2009.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-25 is/are pending in the application.
 4a) Of the above claim(s) 17-25 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-16 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 01 September 2006 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20 April, 2007</u> . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claim s 1-16 in the reply filed on 14 August 2009 is acknowledged. The traversal is on the ground(s) that a search for the subject matter of any one group of claims would encompass a search for the subject matter of the remaining claims. In this regard, Applicants respectfully submit that the Examiner would not hesitate to cite disclosures relating to one group against the remaining groups. This is not found persuasive because the inventions listed as Groups 1-4 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The special technical feature of Groups 1-4 is a formulation comprised of a sensitive active material, an excipient wherein at least 0.1% by wt of the mixture is in an amorphous state. The a formulation comprised of a sensitive active material, an excipient wherein at least 0.1% by wt of the mixture is in an amorphous state of claim 1 does not present a contribution over the prior art. As disclosed in Chang, et al., Pharm. Res., vol. 13, no. 2, 1996, pg 245 first paragraph the protection of a sensitive active material, in this case a protein, mixed with mannitol and glycine was improved with the addition of sucrose, an excipient known to remain amorphous of instant claim 1 is not novel. As such, Group 1 does not share a special technical feature with the instant claims of Group 2-4. Therefore, the claims are not so linked within the meaning of PCT Rule 13.2 so as to form a single inventive concept, and unity between Groups 1-4 is broken.

The requirement is still deemed proper and is therefore made **FINAL**.

Claims 17-25 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 14 August, 2009.

Status of the Claims

Claims 1-16 are treated on the merits in this action.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 20 April, 2007 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired.

See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where

broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation from 0.01 . . . to 50% by wt of the sensitive active material, the claim further recites ". . . preferably from 0.1, more preferably from 0.5 to 50% . . ." which is the narrower statement of the range/limitation; claim 1 is also indefinite in that it recites the broad recitation 50 to 99.99% wt of the excipient, and the claim also recites preferably to 99.9, more preferably to 99.5% which is the narrower statement of the range/limitation.

Claim 2 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex*

parte Steigewald, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 2 recites the broad recitation "0.1 to 50% wt", and the claim also recites "preferably from 0.5, more preferably from 1 to 50 % by wt" which is the narrower statement of the range/limitation.

Claim 3 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired.

See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 3 recites the broad recitation "0.01 to 50% wt", and the claim also recites "preferably from 0.1, more preferably from 0.5 to 50 % by wt" which is the narrower statement of the range/limitation; claim 3 is also indefinite in that it recites the broad recitation "50 to 99.99% wt" of the excipient, and the claim also recites "preferably to 99.9, more preferably to 99.5%" which is the narrower statement of the range/limitation.

Claim 4 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 4 recites the broad recitation "0.01 to 50% wt", and the claim also recites "preferably from 0.1, more preferably from 0.5 to 50 % by wt" which is the narrower statement of the range/limitation; claim 4 is also indefinite in that it recites the broad recitation "50 to 99.89% wt" of the excipient, and the claim also recites "preferably to 99.8, more preferably to 99.4%" which is the narrower statement of the range/limitation.

Claim 5 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the

resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 5 recites the broad recitation "0.01 to 25% wt" of sensitive material, and the claim also recites "preferably from 0.1, more preferably from 0.5 to 25 % by wt" of sensitive material which is the narrower statement of the range/limitation; claim 5 is also indefinite in that it recites the broad recitation "75 to 99.49% wt" of the excipient, and the claim also recites "preferably to 99.4, more preferably to 99%" of the excipient which is the narrower statement of the range/limitation.

Claim 8 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this

can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 8 recites the broad recitation 0.1 to 10% by wt, and the claim also recites 1 to 10% by wt which is the narrower statement of the range/limitation.

Claim 14 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 14 recites the broad recitation which has a hygroscopicity of less than 5%, and the claim also recites

preferably less than 3% by weight, more preferably less than 2% by weight which is the narrower statement of the range/limitation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 6-16 rejected under 35 U.S.C. 102(b) as being anticipated by Maa, WO 02/101412 A2, 19 December, 2002 as evidenced by Surana, Pharm. Res., Vol 21, No. 7, July 2004.

Page 8, line 10 describes a formulation (Formulation 156-57-1) prepared by spray freeze drying a solution of 10 % BSA (i.e. a protein, a sensitive active material), 36% trehalose, 36% mannitol and 18% alanine. The formulation describes a freeze dried mixture of 10% sensitive active material and (36+36+18) 90% excipient, these percentages anticipate the ranges of claim 1. The Surana reference teaches that freeze-drying or spray drying gives an at least partially amorphous product page 1173, col. 1, paragraph 2 stating "crystallization was incomplete even after isothermal annealing at temperatures close to melting. Therefore it is reasonable to conclude that Maa teaches a product which inherently meets the limitation of "at least 0.1% by wt (claim 1) or 1-50% (claim 2) of the mixture is in an amorphous state." Maa anticipates the subject matter of claim 1 and 2 as evidenced by Surana.

As the prior art teaches a composition substantially identical to that in claim 1, and there is evidence tending to show inherency, the burden is shifted to applicant to provide evidence that this is not the case. See MPEP 2112, V.

Maa, pg. 27, line 8 “Suitable amorphous saccharides” anticipates instant claim 6.

Maa, pg. 27, line 13 “Suitable crystalline carbohydrates, sugars and sugar alcohols,” anticipates instant claim 7.

Maa, pg. 70, formulation 156-80-3 teaches 0.1 % methionine and 0.1% Tween 80, anticipating instant claim 8.

Methionine is an antioxidant thus Maa anticipates instant claim 9.

Maa, pg. 20, line 23 teaches polypeptide, anticipating instant claim 10.

Maa, pg. 22, line 14 teaches bacterium, anticipating instant claim 11

Maa, pg. 27, line 14 teaches the composition is comprised of a crystalline excipient with an amorphous excipient, anticipating instant claim 12.

As Maa meets the structural limitations of claim 1, and function is inseparable from structure, the burden is shifted to applicant to show the compositions of Maa do not possess the reduced hygroscopicity as in instant claims 13 and 14. MPEP 2112, I, the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Maa, pg. 34, line 17, teaches a single unit dosage, anticipating instant claim 15.

Maa, pg. 34, line 20 teaches a sterile formulation package, anticipating instant claim 16.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-16 rejected under 35 U.S.C. 103(a) as being unpatentable over Maa, WO 02/101412 A2, 19 December, 2002 as evidenced by Surana, Pharm. Res., Vol 21, No. 7, July 2004.

As discussed above, Maa teaches compositions which anticipate or in the alternative render obvious the compositions of instant claims 1 and 2.

Maa does not specifically teach a composition with an amorphous excipient in the range of 1-5%; however Maa does explicitly teach the use of amorphous excipients down to 10 percent (pg. 28, line 4) and explicitly teaches the addition of a surfactant (pg. 28, line 8-9) in an amount from 1-5% by weight. Therefore, while Maa does not expressly use the same terminology as applicant, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to provide a composition with an amorphous excipient as in instant claims 3-5 because Maa suggests the use of an excipient in the range of 1-5% w/w and teaches the excipients may be amorphous or crystalline. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

MPEP 2144.05

Accordingly, the claimed invention of instant claims 1-5 was prima facie obvious to one of ordinary skill in the art at the time the invention was made especially in the absence of evidence to the contrary.

It would have been obvious to provide a formulation in which a saccharide is used to provide an excipient in an amorphous state given the teaching of Maa, pg. 27, line 8 “Suitable amorphous saccharides”.

Maa, pg. 27, line 8 “Suitable amorphous saccharides” renders obvious instant claim 6.

Maa, pg. 27, line 13 “Suitable crystalline carbohydrates, sugars and sugar alcohols,” renders obvious instant claim 7.

Maa, pg. 70, formulation 156-80-3 teaches 0.1 % methionine and 0.1% Tween 80, rendering obvious instant claim 8.

Methionine is an antioxidant thus Maa renders obvious instant claim 9.

Maa, pg. 20, line 23 teaches polypeptide, rendering obvious instant claim 10.

Maa, pg. 22, line 14 teaches bacterium, rendering obvious instant claim 11

Maa, pg. 27, line 14 teaches the composition is comprised of a crystalline excipient with an amorphous excipient, rendering obvious instant claim 12.

As Maa meets the structural limitations of claim 1, and function is inseparable from structure, the burden is shifted to applicant to show the compositions of Maa do not possess the reduced hygroscopicity as in instant claims 13 and 14. MPEP 2112, I, the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Maa, pg. 34, line 17, teaches a single unit dosage, rendering obvious instant claim 15.

Maa, pg. 34, line 20 teaches a sterile formulation package, rendering obvious instant claim 16.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to WILLIAM CRAIGO whose telephone number is (571)270-1347. The examiner can normally be reached on Monday - Friday, 7:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

William Craig
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/Leon B Lankford/
Primary Examiner, Art Unit 1651